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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,966	12/05/2001	Wesley H. Verkaart	70869-0083	1396

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HAEMONETICS CORPORATION
400 WOOD ROAD
BRAINTREE, MA 02184-9114

EXAMINER	
SAUCIER, SANDRA E	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,966	VERKAART ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 21-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11, 21-23 are pending and are considered on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1-3, 5-10, 21-23 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dorner *et al.* [U].

The claims appear to be directed to a method for separating red cells from a mixture (having a hematocrit about 30-64) comprising blood, anticoagulant and a washing solution (starch), whereby the anticoagulant consists essentially of an inert anticoagulant (CPD or heparin) by sedimentation in the absence of centrifugation (unit sedimentation or gravity sedimentation).

Dorner *et al.* teach a method of separation of red cells from a mixture having a hematocrit of 30-35 comprising blood, CPD and hydroxyethylstarch by gravity sedimentation. (Materials and Methods, page 440).

Claims 1, 4, 5, 6, 11, 21-23 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 4,765,899 [A].

The claims appear to be directed to a method for separating red cells from a mixture (having a hematocrit about 30-64) comprising blood, anticoagulant and a washing solution (starch), whereby the anticoagulant consists essentially of an inert anticoagulant (CPD or heparin) by sedimentation in the absence of centrifugation.

US 4,765,899 disclose in Example 1 a method for separating components of blood comprising adding heparin as anticoagulant to blood, adding HES (ACD) and using unit gravity sedimentation. The blood is in the sedimentation chamber for about 15-20 minutes.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Hertz, 537 F.2d 549, 551 - 52, 190 USPQ 461, 463 (CCPA 1976)(emphasis in original)(Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well - known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). See also Atlas Powder Co. v. E.I. duPont de Nemours & Co. , 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama - Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. v. Calco, Ltd ., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988).

When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063 - 64 (Bd. Pat. App. & Inter. 1989)("Although `consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps . . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification . . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by `consisting essentially of' language.").

Claim Rejections - 35 USC § 103

Claims 1-11, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,879,318 [IDS] in combination with Dorner *et al.* [U].

The claims appear to be directed to a method for separating red cells from a mixture (having a hematocrit about 30-64) comprising blood, anticoagulant and a washing solution (starch), whereby the anticoagulant is inert (CPD or heparin) by sedimentation in the absence of centrifugation. The sedimented cells are resuspended prior to transfusion.

The references are relied upon as explained below.

US 5,879,318 discloses a composition comprising blood, CPD and a rouleaux reagent comprising Hetastarch (col. 5, l. 48, and col. 6, l. 20-29 and claim 3. The HES solution is 6% (col. 3, l. 21). The blood/anticoagulant 7:1 mixture (col. 5, l. 47) is mixed with the starch and the red cells sedimented (col. 6, l. 1-9) and the supernatant containing the white cells is removed (col. 5, l. 31-38). US 5,879,318 further teaches the use of heparin among other anticoagulants and exemplifies CPD as the anticoagulant of choice in a composition comprising blood, anticoagulant and HES (col. 4, l. 44). The use of a short centrifuge spin red cells aids in the sedimentation of the red cells (col. 2, l. 26). However, this is an optional aid in the sedimentation process. Thus, the reference teaches both sedimentation under gravity alone and aided by mild centrifugation.

Dorner *et al.* teach the time for gravity sedimentation using CPD/HES is about 25 minutes. In Fig 1, times of sedimentation up to 35 minutes are exemplified.

It would have been obvious to use heparin as an anticoagulant in a ratio of 1/7 in a process of adding HES, preferably between 1-6% (col. 4, l. 40) and forming a mixture of blood, heparin 7/1 and 6% HES in order to sediment red

cells because '318 generically teaches this method in the absence of unexpected results.

In the absence of evidence to the contrary, such as unexpected results, and it is noted that no working examples are present in the specification, the claims directed to the use of heparin as an anticoagulant are considered to be obvious over the cited prior art.

It would have been obvious to allow the red cells to sediment by gravity for about 20 minutes when '318 was taken with Dorner *et al.* because Dorner *et al.* disclose the time for gravity sedimentation with anticoagulant (CPD)/HES is about 25 minutes.

One of ordinary skill in the art would have been motivated at the time of invention to make this substitution in order to obtain the results as suggested by the reference with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Argument

Applicant's arguments filed 11/22/04 have been fully considered but they are not fully persuasive.

Applicants argue that their method is limited to shed blood which are useful when the blood is collected from a patient and the red cells washed and returned to the patient.

All blood is shed as the definition of "shed" is "to cause to flow in a stream or fall in drops". See page 1235 of the attached Webster's New World Dictionary. Thus, arguments based on "shed" blood as opposed to, one supposes, unshed blood are not persuasive. Further, applicants appear to

argue intended use for the claimed method. Intended use of the claimed method is of little patentable weight.

Applicants argue that US 4,765,899 uses in Example 1, ACD solution, and that the specification teaches the avoidance of ACD-A solution. Please note that "ACD" in the example of the prior art refers to anticoagulant-citrate-dextrose of which the anticoagulant is heparin. The instant specification refers to ACD-A which is not defined in the specification, but which clearly is not heparin-citrate-dextrose. Applicants' arguments are not persuasive of error.

Applicants continue to argue that US'318 discloses centrifugation in the process. However, as pointed out in the previous office action, use of centrifugation to aid sedimentation is optional. Applicant has not provided any working examples or direct comparisons with the prior art to show unexpected results to overcome the obviousness rejection. Use of the term "shed" blood does not differentiate the instant process from the prior art as explained above.

In short, the method as claimed is old and known in the art. No claim is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period; then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sandra Saucier
Primary Examiner
Art Unit 1651
January 18, 2005